NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., et al., **Plaintiffs,** **v.** **TEVA PHARMACEUTICALS USA, INC.,** **Defendant.**	**Civil Action No. 08-1331 (DMC)** **OPINION**

Currently before the Court is an informal motion to compel the production of certain documents, filed by Defendant Teva Pharmaceuticals USA, Inc. (hereinafter "Teva"). In particular, Teva seeks the production of two general categories of documents: (1) all documents concerning all controlled release formulations of tolterodine that Pfizer considered, tested or developed, and (2) all documents concerning the expiration or loss of Pfizer's exclusivity to market tolterodine tartrate. The Court has considered the letters submitted in support of and in opposition to the instant motion, none of which were filed on the Court's electronic docket given the confidential information contained therein. Based on the reasons that follow, Teva's motion to compel is **granted in part and denied in part**.

BACKGROUND

Pfizer is the owner of United States Patent No. 6,770,295 ("the '295 patent"). The '295 patent covers a pharmaceutical formulation technology that provides for the extended release of tolterodine, as embodied by the drug manufactured by Pfizer under the trade name Detrol ® LA.[1]

[1] LA stands for "long acting."

Detrol ® LA is administered for the treatment of urinary incontinence.

Teva filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food & Drug Administration ("FDA") for a generic copy of Detrol ® LA, pursuant to the Hatch-Waxman Act. Teva has not yet received FDA approval of its generic. Nevertheless, its decision to seek FDA approval before expiration of the '295 patent is considered an act of infringement under the Hatch-Waxman Act. As a result, Pfizer sued Teva for patent infringement after receiving notice of Teva's ANDA filing.

DISCUSSION

Teva now moves to compel Pfizer to produce two categories of documents: (1) all documents concerning all controlled release formulations of tolterodine that Pfizer considered, tested or developed, and (2) all documents concerning the expiration or loss of Pfizer's exclusivity to market tolterodine tartrate. The Court will now address each category, in turn.

1. Documents Concerning All Controlled Release Formulations of Tolterodine

Teva seeks production of all documents concerning all controlled release formulations of tolterodine, including the transdermal controlled release formulation of same. As a preliminary matter, the Court notes that Pfizer's Detrol ® LA product and Teva's proposed generic product are oral dosage forms. Pfizer represents that it has never marketed a transdermal formulation of tolterodine and Teva has never sought regulatory approval to do so. Moreover, it is undisputed that Pfizer's claims in this case are limited to oral, as opposed to transdermal, formulations of tolterodine. Nevertheless, Teva seeks documents concerning all controlled release formulations, including the transdermal formulation, on the basis that Pfizer had also asserted several broad "controlled release

formulation" claims, which could be construed to include both oral and transdermal controlled release formulations of tolterodine. In addition, Teva argues that such documents are relevant to several of its defenses.[2] In response, Pfizer has agreed to produce all documents concerning oral controlled release formulations of tolterodine. Therefore, those documents are no longer at issue. With respect to Teva's request for documents concerning the transdermal controlled release formulation of tolterodine, Pfizer has now narrowed its infringement contentions to the four claims of the '295 patent that are explicitly limited to oral formulations. To be clear, Pfizer has not asserted the "transdermal claims" of the '295 patent against Teva, and has now dropped those broadly defined "controlled release formulation" claims.

Nevertheless, Teva maintains that it is entitled to documents concerning Pfizer's consideration, testing and development of all non-oral formulations of tolterodine, including trasndermal administration, because those documents are relevant to Teva's defenses. In support of this position, Teva argues that "it is likely . . . that the inventors who focused on transdermal administration of tolterodine drafted, produced or received documents concerning other formulations or attended meetings concerning the overall development of controlled release tolterodine products." (Teva Reply Letter dated May 8, 2009). In short, Teva explains that "documents still may be relevant to Teva's defenses even if they do not explicitly refer to oral formulations." (Id.).

In response, Pfizer argues that because transdermal formulations of tolterodine do not fall within any of the claims asserted in this case, the inventors' efforts to develop such formulations are irrelevant to whether the asserted claims are obvious. This Court agrees. In addition, the Court

[2] These include: (1) lack of enablement, (2) obviousness, and (3) other unspecified defenses. By way of letter dated May 8, 2009, Teva conceded that once Pfizer dropped the broad "controlled release formulation" claims, Teva's arguments based on the nonenablement defense became moot.

finds that Teva's claims of relevance as to those documents concerning non-oral controlled release formulations of tolterodine are purely speculative.[3] Accordingly, Teva's motion to compel the production of all documents concerning all controlled release formulations of tolterodine is **granted** as to those documents concerning oral controlled release formulations of tolterodine. To the extent Teva seeks documents concerning the transdermal release formulation, in a case where no such transdermal release formulation claims have been asserted, Teva's request is **denied.**

2. Documents Concerning the Expiration or Loss of Pfizer's Exclusivity to Market Tolterodine Tartrate

Teva describes that according to recent publicly available information, Pfizer has immediate plans to cease all marketing of the Detrol ® brand, including Detrol ® LA, and to "cannibalize" the Detrol ® LA market with a new follow-up product for overactive bladders, Toviaz ® extended release tablets. In this regard, Teva moves to compel the production of documents concerning Pfizer's decision to "cannibalize" its Detrol ® LA market in favor of Toviaz ®. Teva maintains that these documents are relevant to Teva's obviousness defense inasmuch as Pfizer has stated that it intends to rely on sales data for Detrol ® LA, and the commercial success of same, as objective indicia of nonobviousness. Therefore, according to Teva, since Pfizer will raise the "commercial success" of Detrol ® LA in response to Teva's obviousness defense, Pfizer's plans to eliminate those sales in favor of an entirely separate product not covered by the patents-in-suit are plainly relevant. Such evidence, including Pfizer's marketing strategies and the forecasted impact of Toviaz ® on

[3] This is not to say, however, that this type of evidence can never be relevant. To the contrary, the Court merely finds that in this particular case, the basis of relevance set forth is far too speculative.

Detrol ® LA would show, according to Teva, that Pfizer believes the so-called "commercial success" of Detrol ® LA is entirely due to Pfizer's promotional and advertising efforts and not at all tied to the patents covering that product.

In response, Pfizer argues that its marketing strategy for Toviaz ® is highly confidential and irrelevant to the issues in this case. In particular, Pfizer argues that Teva's position is based entirely on speculation and contingencies that may never happen. For instance, according to Pfizer, Teva's position is based on the presumption that a future decline in sales of Detrol ® LA due to the introduction of Toviaz ® would be relevant to the issue of commercial success. According to Pfizer, however, sales of Detrol ® LA have yet to decline. Moreover, Toviaz ® was only launched several weeks ago. Therefore, according to Pfizer, their plans for a product that has just entered the market cannot be probative of whether a decade of ongoing commercial success of Detrol ® LA has a nexus with the patents-in-suit. Finally, Pfizer argues that it holds no such belief that the "commercial success" of Detrol ® LA is entirely due to Pfizer's promotional and advertising efforts, and, in any event, Pfizer's own beliefs about the success of its product are irrelevant, as only objective indicia are evidence of nonobviousness.

In support of its position, Teva relies on McNeil-PPC, Inc. v. Perrigo Co., 516 F.Supp. 2d 238 (S.D.N.Y. 2007), where the court held, according to Teva, that evidence that the brand company had "cannibalized" one product in favor of another patented product showed that the so-called "commercial success" of the patented product was due to the brand company's substantial promotional campaign and not to the patented invention. Having reviewed the McNeil-PPC, Inc. decision, the Court finds that the portion relied upon by Teva is distinguishable from the case at bar. For instance, the McNeil-PPC, Inc. decision involved several patents comprising the over the counter

drug, Pepcid Complete. The crux of the relevant issue in that case had to do with the commercial success of Pepcid Complete, which was raised in response to Defendant's obviousness defense. Because Plaintiff had successfully sold the drug Pepcid AC prior to the launch of Pepcid Complete, and then chose to take Pepcid AC off the market once Pepcid Complete had entered the market, the Court found that "[t]his raises an inference that Pepcid Complete's success is derived at least in part from the cannibalization of Pepcid AC." Id. at 254. In addition, the Court commented that the launch for Pepcid Complete was substantial; therefore, "[t]he inference of non-obviousness arising from commercial success is weakened where the patentee's 'promotional campaign contributed to the patented [product's] commercial success.' " Id.

By contrast, the issue here is not whether Detrol ® LA has impacted the commercial success of Toviaz ® – the subsequently launched drug in this case. In fact, the commercial success of Toviaz ® is entirely irrelevant to this case. Equally irrelevant to the analysis of whether the patent comprising Detrol ® LA is invalid as obvious would be any subjective beliefs allegedly held by Pfizer with respect to its commercial success. See, e.g., KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 399 (2007) (utilizing an objective analysis for resolving the obviousness question); McNeil-PPC, Inc., 516 F. Supp. 2d at 247 (noting that commercial success is an objective consideration). In short, Teva cites to no caselaw for the proposition that Pfizer's internal strategy for the launch of a new product relates – in any way – to the level of commercial success Detrol ® LA has amassed since entering the market in 2001. Accordingly, Teva's request for documents concerning Pfizer's marketing strategies behind the launch of Toviaz ® and its forecasted impact on Detrol ® LA is **denied.**

CONCLUSION

Based on the reasons set forth above, Teva's motion to compel the production of certain documents is granted in part and denied in part. An appropriate Order accompanies this Opinion.

/s/ Mark Falk
MARK FALK
United States Magistrate Judge

DATE: June 4, 2009

Orig.: Clerk of the Court
cc: Hon. Dennis M. Cavanaugh, U.S.D.J.
All Parties